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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities;
Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: "Improving Sickle Cell Transitions of Care through Health Information Technology Phase 1." In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501-3521, AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously published in the Federal Register on February 7th, 2013 and allowed 60 days for public comment. No comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by (insert date 30 days after date of publication).

ADDRESSES: Written comments should be submitted to: AHRQ's OMB Desk Officer by fax at (202) 395-6974 (attention: AHRQ's desk officer) or by email at OIRA_submission@omb.eop.gov (attention: AHRQ's desk officer).

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427-1477, or by email at doris.lefkowitz@AHRQ.hhs.gov.

SUPPLEMENTARY INFORMATION:

Proposed Project

Improving Sickle Cell Transitions of Care through Health Information Technology Phase I

This project is the first phase in AHRQ's effort toward the development of a health information technology (HIT) enabled tool designed to aid adolescents and young adults with sickle cell disease (SCD) during transitions of care. SCD is a serious, genetic blood disorder that affects approximately 70,000 - 100,000 Americans, including one out of every 500 African American and one out of every 36,000 Hispanic American births. Persons with SCD produce abnormal, "sickle-shaped" red blood cells that obstruct blood vessels, leading to life-long anemia, organ damage, increased potential for infections, chronic episodes of pain, and substantially shortened life spans. SCD has been noted to be understudied relative to its prevalence resulting in a lack of knowledge about

the important variables and domains that determine health outcomes for patients. Furthermore, patients with SCD, typically young, minority, and often of lower income status, have had few opportunities to voice their needs and concerns about their health and health care.

As recently as 30 years ago, children with SCD usually did not survive into adulthood. Now, as a result of advances in screening and treatment, more than 90 percent of individuals with SCD reach adulthood, and life expectancy is typically into the fifth decade. Persons with SCD experience multiple transitions of care as a result of the chronicity of SCD, frequency of both acute and chronic-events requiring care, as well as the advancements in life expectancy. Transitions of care occur when either the setting of care changes (e.g., from home-based to hospital-based care) or the focus of care changes (e.g., from pediatric-focused to adult-focused care). When transitions of care occur, a need to share medical history and other types of health information arises. Transitions of care are more likely to be successful when this health information is accurate, tailored to the type of transition taking place, and communicated effectively.

Times of care transitions are particularly fraught for patients with SCD and currently, few patients have access to effective transition programs for SCD. In a 2010 survey of pediatric SCD providers, the majority claimed to have transition programs in place but they were often newly formed and without the ability to transfer care to adult providers with specific expertise in SCD.

Preliminary evidence suggests that HIT can be helpful for SCD and similar conditions. In particular, a technology-based tool has already been used successfully by patients with SCD to help with some aspects of disease management. In one study, a handheld wireless device was used to implement a pain management protocol and found to result in high rates of participation and satisfaction. Technology-based tools or applications - "apps" - have also been effective in improving care transitions for other chronic diseases such as diabetes and HIV, which can serve as models for this tool.

Improving transitions of care is the focus of AHRQ's plans to respond to the Department of Health and Human Services' (HHS') SCD Initiative announced in 2011. The overall HHS SCD initiative, which is aligned with AHRQ' s mission, aims to improve the health of persons with SCD through various activities, including developing and disseminating evidence-based guidelines, increasing the availability of medical homes that provide SCD care, and supporting research in areas such as pain and disease management, all of which could also be supported through the use of an effective HIT enabled tool.

The goals of this project are to:

1) Gain the necessary background knowledge including qualitative information from key stakeholders, to establish a set of requirements that would guide the design and development of a HIT-enabled tool in future phases of work that meets patients,' families,' and providers' needs to aid adolescents and young adults with sickle cell disease during transitions of care.

2) Develop an understanding of the environmental context, current facilitators and barriers, health data use and needs of key stakeholders affected by sickle cell disease, including patients, families, and providers.

This study is being conducted by AHRQ through its contractor, The Lewin Group in partnership with Children's National Medical Center, Cincinnati Children's

Hospital Medical Center, Nemours Children's Clinic-Jacksonville, and the National Initiative for Children's Healthcare Quality, pursuant to AHRQ's statutory authority to conduct and support research on healthcare and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of healthcare services and with respect to quality measurement and improvement. 42 U.S.C. 299a(a)(1) and (2).

Method of Collection

To achieve the goals of this project, the following activities and data collections will be implemented:

1) Environmental Scan - AHRQ will execute a literature review to identify potentially relevant scientific literature and information from other literature and sources as well as complete a search for existing tools that aid transitions of care for persons with SCD or similar conditions. This will provide contextual background about the current state of the field with regards to tool-development and use, identify key-issues of patients with SCD related to care transitions, and understand the context of care delivered and health data information needs to inform the content, design and functionality of a tool. This activity does not impose a burden on the public and is not included in the burden estimates in Exhibit 1.

2) Focus Groups - AHRQ will facilitate ten focus groups of key stakeholder groups including: parents/caregivers of patients with SCD; health care providers (e.g. SCD specialists, primary care physicians (PCPs), hospitalists and emergency room (ER) physicians); IT developers; SCD patients ages 9-13; SCD patients ages 14-17; SCD patients 18 and older; and SCD patients of mixed ages; to gather qualitative information on stakeholder experiences with SCD and care transitions, barriers to quality care, and use of technology to inform tool design and functionality. Each group will consist of 10 participants and will be asked to describe their particular experiences with health care transitions, communication practices, information needs and technology use in order to develop relevant "use cases" which will be used by investigators and tool developers for the later phases of the project. The in-person nature of focus groups allows for a more in-depth and targeted discussion, including participant experiences, impressions and priorities in a detailed fashion.

3) Demographic Questionnaire - AHRQ will implement a short demographic questionnaire at the start of each of the ten focus groups to collect basic demographic information to allow the team to contextualize findings from each focus group. Questionnaires are tailored to each focus group category: parents/caregivers of patients with SCD; providers, hospitalists and ER physicians; IT developers; SCD patients ages 9-13; SCD patients ages 14-17; SCD patients 18 and older; and SCD patients of mixed ages.

4) Key Informant Interviews - AHRQ will conduct eight key informant interviews with stakeholders such as State Medicaid representatives, attorneys with expertise in privacy and security issues, representatives from the Office of the National Coordinator for Health Information Technology (ONC), Office of Chief Scientist, and other relevant policy makers. Qualitative information gained will contribute to tool development recommendations particularly in terms of cost issues related to reimbursement by payers, needs for proof of effectiveness, sustainability, and potential vehicles for facilitating and funding tool development and implementation.

The information gained from the focus groups and key informant interviews will be used to understand if and how a patient-centered, HIT-enabled tool can improve the health of individuals with SCD during care transitions.

Focus groups as a form of qualitative research are an important vehicle for gathering and explicating insight from the field, especially if, as in this case, the important domains are not yet understood, and need to be outlined by respondents, rather than suggested by investigators. Thus active recruitment and qualitative techniques are a means to incorporate this necessary and important perspective into the derivation of effective interventions. The primary objective of the focus groups is to gather more richly nuanced information from sickle cell disease stakeholders. The in-person nature of focus groups allows for a more in-depth and targeted discussion, including participant experiences, impressions and priorities in a detailed fashion.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondents' time to participate in this research. The demographic questionnaire will be completed by each focus group participant and takes 6 minutes to complete. All of the focus groups and key informant interviews will last 2 hours except for the IT developer focus group which will last 4 hours. Each focus group will consist of 10 persons. There will be two focus groups with providers, three with parents/caregivers, one group for IT developers, and one focus group with each of the four patient groups. Key informant interviews will be conducted with eight individuals. The total burden is estimated to be 246 hours annually.

Exhibit 2 shows the estimated annualized cost burden associated with the respondents' time to participate in this research. The total cost burden is estimated to be $8,174
annually.

Exhibit 1. Estimated annualized burden hours

Form Name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Demographic Questionnaire	100	1	6/60	10
Provider Focus Groups	20	1	2	40
Parent/Caregiver Focus Groups	30	1	2	60
IT Developer Focus Group	10	1	4	40
Patients 9-13 Focus Group	10	1	2	20
Patients 14-17 Focus Group	10	1	2	20
Patients 18 & older Focus Group	10	1	2	20
Patients mixed ages Focus Group	10	1	2	20
Key Informant Interviews	8	1	2	16
Total	208	na	na	246

Exhibit 2. Estimated annualize cost burden

Form Name	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
Demographic Questionnaire	100	10	$26.89\a\	$269
Provider Focus Groups	20	40	$88.78\b\	$3,551

Parent/Caregiver Focus Groups	30	60	$21.74\c\	$1,304
IT Developer Focus Group	10	40	$44.27\d\	$1,771
Patients 9-13 Focus Group	10	20	$0\e\	$0
Patients 14-17 Focus Group	10	20	$0\e\	$0
Patients 18 & older Focus Group	10	20	$21.74\c\	$435
Patients mixed ages Focus Group	10	20	$0\e\	$0
Key Informant Interviews	8	16	52.72\f\	$844
Total	208	246	na	$8,174

\a\ Based on the mean wages for Physicians & Surgeons, All other (29-1069), All Occupations (00-0000), Software Developer (15-1132). Wages for children averaged in as $0.
\b\ Based on the mean wages for Physicians & Surgeons, All other (29-1069)
\c\ Based on the mean wages for All Occupations (00-0000)
\d\ Based on the mean wages for Software Developer (15-1132)
\e\ No wage data for children
\f\ Based on the mean wages for Lawyers (23-1011), Social and Community Service Managers (11-9151), Medical and Health Services Managers (11-9111), and Computer and Information System Managers (11-3021)
*National Compensation Survey: Occupational wages in the United States May 2011, "U.S. Department of_Labor, Bureau of Labor Statistics."
http://www.bls.gov/oes/current/oes_nat.htm#15-0000

Estimated Annual Costs to the Federal Government

Exhibit 3 shows the estimated total and annualized cost to the federal government over 18 months. The total cost to the federal government of this data collection effort is $264,043. This figure includes development of draft and final plans for conducting focus groups and interviews; development of materials including moderator guides for each stakeholders group (seven guides in total), recruitment materials for all four sites, consent forms; facilitating IRB approval processes at four sites; logistics coordination including securing facility space; recruitment of participants; incentives for participants (as described in section 9 above); and analyzing and summarizing findings as well as preparing final reports.

Exhibit 3. Estimated Total and Annualized Cost

Cost Component	Total Cost	Annualized Cost
Project Development	$23,689	$15,793
Data Collection Activities	$169,586	$113,057
Data Processing and Analysis	$16,000	$10,667
Publication of Results	$33,472	$22,315
Project Management	$18,319	$12,213
Overhead	$2,977	$1,985
Total	$264,043	$176,029

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and

clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology. Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: April 15, 2013

Carolyn M Clancy,
Director

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